

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent Application No. 10/806,088

Confirmation No. 1687

Applicant: Flack et al.

Filed: March 22, 2004

TC/AU: 1614

Examiner: James D. Anderson

Docket No.: 225011 (Client Reference No. E-133-1990/0-US-03)

Customer No.: 45733

**RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the "Notification of Non-Compliant Appeal Brief" dated June 11, 2008, Applicants submit the corrected section "Claims Appendix" for "Appellants' Appeal Brief" dated August 17, 2007.

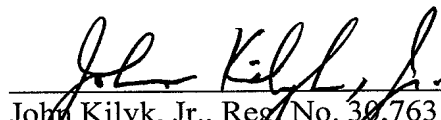
The "Claims Appendix" has been revised to reflect the correct status identifier of claim 16. Claim 16 is a new claim that was added in the "Amendment and Statement of Status/Support for Claim Changes Pursuant to 37 CFR § 1.173" submitted March 22, 2004. As such, claim 16 has been underlined in the "Claims Appendix."

Appellants confirm that claims 11-14 of the "Claims Appendix" of "Appellants' Appeal Brief" are the claims 11-14 that are on appeal. In the "Reply to Office Action" dated February 2, 2006, claims 11-14 were amended to replace "said compound" with "(-)-gossypol or a physiologically acceptable salt thereof." The amendments to claims 11-14 were not reflected in subsequent replies (i.e., the "Reply to Office Action" dated October 20, 2006, the "Reply to Office Action" dated February 22, 2007, and the "Reply to Office Action" dated May 14, 2007) or "Appellants' Appeal Brief" dated August 17, 2007. However, although it

was not particularly addressed in the subsequent replies or the appeal brief, Appellants removed these amendments to claims 11-14 (which replaced "said compound" with "(-)-gossypol or a physiologically acceptable salt thereof") in view of the amendment of claim 8 in the "Reply to Office Action" dated February 22, 2007. Accordingly, claims 11-14 of the "Claims Appendix" of "Appellants' Appeal Brief" (as well as the "Claims Appendix" submitted herewith) are the appealed claims 11-14. The claim identifiers for claims 11 and 12-14 have been changed to "Once Amended" and "Original," respectively, to reflect the status of the claims relative to the claims of the patent.

Appellants note that the remaining status identifiers also have been revised. In particular, (i) "Pending – Never Amended" has been replaced with "Original," (ii) "Pending – Fourth Amendment" has been replaced with "Four Times Amended," and (iii) "Pending – New" has been replaced with "New."

Respectfully submitted,

  
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*Claims Appendix*

1. (Canceled) [A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a physiologically acceptable salt of gossypol, gossypolone, a physiologically acceptable salt of gossypolone, or any combination thereof, which method comprises:

administering to said human an anti-cancer effective amount of at least one compound selected from the group consisting of gossypol, a physiologically acceptable salt of gossypol, gossypolone, and a physiologically acceptable salt of gossypolone, and a pharmaceutically acceptable carrier.]

2. (Canceled) [The method of claim 1, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.]

3. (Canceled) [The method of claim 2, wherein said cancer is adrenal cancer.]

4. (Canceled) [The method of claim 1, wherein the blood concentration of said compound is 400-1000 ng/dl.]

5. (Canceled) [The method of claim 4, wherein said compound is gossypolone or a physiologically acceptable salt of gossypolone.]

6. (Canceled) [The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered orally, rectally or vaginally at a dose of 50-200 mg/d.]

7. (Canceled) [The method of claim 5, wherein said gossypolone or physiologically acceptable salt of gossypolone is administered parenterally at a dose of 1-5 mg/kg/d.]

8. (Four Times Amended) A method for treating a cancer in a human, wherein the cancer is susceptible to treatment with gossypol, a [pharmaceutically] physiologically acceptable salt of gossypol, or a combination thereof, which method comprises:

administering to said human a composition comprising an anti-cancer effective

amount of at least one compound selected from the group consisting of gossypol and a physiologically acceptable salt thereof, [and] wherein the at least one compound is administered with a pharmaceutically acceptable carrier, and wherein the at least one compound exhibits an overall effect of rotating the plane of polarized light in the (-) direction.

9. (Original) The method of claim 8, wherein said cancer is adrenal, ovarian, thyroid, testicular, pituitary, prostate, or breast cancer.

10. (Original) The method of claim 8, wherein said cancer is adrenal cancer.

11. (Once Amended) The method of claim 8, wherein the blood concentration of said compound is [400] 200-1000 ng/dl.

12. (Original) The method of claim 8, wherein said compound is administered parenterally at a dose of 1-2 mg/d.

13. (Original) The method of claim 8, wherein said compound is administered orally at a dose of 20-100 mg/d.

14. (Original) The method of claim 8, wherein said compound is administered rectally at a dose of 40-140 mg/d.

15. (Canceled)

16. (New) The method of claim 8, wherein said cancer is a carcinoid tumor of neuroendocrine tissue located in the lung, pancreas, or gastrointestinal tract.

17.-37. (Canceled)

38. (New) The method of claim 8, wherein said cancer is ovarian cancer.

39. (New) The method of claim 8, wherein said cancer is thyroid cancer.

40. (New) The method of claim 8, wherein said cancer is testicular cancer.

41. (New) The method of claim 8, wherein said cancer is pituitary cancer.

42. (New) The method of claim 8, wherein said cancer is prostate cancer.

43. (New) The method of claim 8, wherein said cancer is breast cancer.